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09/720,943	03/12/2001	Brigitte Wittmann-Liebold	101215-52	8319

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,943

Applicant(s)

WITTMANN-LIEBOLD ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/07/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cooling elements (3) arranged between the gel chambers (6,7) must be shown or the feature canceled from the claims. No new matter should be entered. Figure 4 shows the gel chambers separated by an isolating hose (9). The cooling elements shown in Figure 2 are to be located underneath the gels (second full paragraph on page 12 of the specification).

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cover covering "off the electrophoresis combination chamber (1) in the upward direction" must be shown or the feature canceled from the claims. No new matter should be entered. Figure 1 shows the cover covering the top of the electrophoresis combination chamber.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 4, 17, 20, 26, and 27 are objected to because of the following informalities:
- a) Claim 4, line 5: "rising" should be -- rises --;
 - b) Claim 17, line 5: "The use of reference characters is to be considered as having no effect on the scope of claims." MPEP 608.01(m). So "the gels (25) and (36)" should be - -- gels (25 and 36) --;
 - c) Claim 17, line 9: which plate? "The use of reference characters is to be considered as having no effect on the scope of claims." MPEP 608.01(m);
 - d) Claim 17, line 10: which plate? "The use of reference characters is to be considered as having no effect on the scope of claims." MPEP 608.01(m);
 - e) Claim 20, line 6: -- it -- should be inserted between "by" and "drawing";
 - f) Claim 20, line 6: "the removal of" should be -- removing --;
 - g) Claim 26, line 3: "3,5-4,5%" should be -- 3.5-4.5% --;

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h) Claim 26, line 3: "3,5-5%" should be -- 3.5-5% --; and

i) Claim 27, line 3: "5-9,5 M" should be -- 5-9.5 M --.

4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Claim 1 requires "the gels for the separation in the first dimension and the gels for the separation in the second dimension, arranged in succession or simultaneously vertical to one another, are brought into an electrophoresis combination chamber as casting gels or as ready-to-use gels and from each other are isolated by a hollow seal." Although the specification mentions an *assembly* having several units

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(presumably combination chambers) in each of which a *single* first dimension gel can be arranged in succession or simultaneously vertical to a *single* second dimension gel, with each gel separated from the other by a hollow seal (page 11, last paragraph – page 12, second paragraph and page 14, lines 7-8), no illustration, description, or mention has been found of a combination chamber in which several first dimension gels are arranged vertically to several second dimension gels and each separated from the other gels by a hollow seal. One with ordinary skill in the art would not know how to adapt the disclosed combination chamber so as to accommodate several first dimension gels and several second dimension gels.

7. Claims 9-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Independent Claims 9 and 15 require the cooling elements to be arranged between the gel chambers. However, no such embodiment has been found in the specification or drawings. Instead, the disclosure only describes or shows embodiments in which the cooling elements are arranged underneath the gels and there is sealing hose between the gels (Figure 2 and second full paragraph on page 12 of the specification). One with ordinary skill in the art at the time of the invention would not know to place cooling elements between the first and second dimension gels so as to effectively control their temperatures, as contact could only be made between the edges of the cooling elements and the

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edges of the gels. Also, how will products of the separation in the first dimension reach the second dimension gel if the cooling elements are in between the gels?

8. Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Claim 16 requires the gels to be arranged horizontally and above each other. However, no such embodiment has been found in the specification or drawings. Instead, the disclosure only describes or shows embodiments in which the gels are arranged in the same plane in a planar structure (Figures 1, 3, and 4). The invention of Claim 16 would require one with ordinary skill in the art to create a new combination chamber having a substantially different structure than any for which guidance is provided.

9. Claims 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. Claim 23 requires polymerizing specimens out of specimen pockets in a comb and into recesses, which are presumably in an SDS gel. No description nor mention of such a method has been found in the specification. For one with ordinary skill in the art to determine the composition of a polymer-forming solution that will

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“polymerize out” certain specimen molecules placed in the polymer-forming solution will require undo experimentation.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a) Claim 1, line 2: “gels, polymer carriers” is unclear. Does Applicant mean -- gel polymer carriers -- , -- gel or polymer carriers --, or something else? Note that “polymer carriers” does not occur again in Claim 1 and does not occur in any claim that depends from Claim 1;
- b) Claim 1 recites the limitation "gels for the separation in the first dimension" in line 3. There is insufficient antecedent basis for this limitation in the claim;
- c) Claim 1 recites the limitation "gels for the separation in the second dimension" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim;
- d) Claim 1, line 6: does one hollow seal separate all of the first dimension gels from the second dimension gels?

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e) Claim 1, lines 8-10 has biomolecule mixture deposited onto all of the first dimension gels, but only one electrophoretic separation in the first dimension. Are the several first dimension gels involved in the single electrophoretic separation or is the first dimension electrophoretic separation only performed in one of the first dimension gels?

f) Claim 1 recites the limitation "the buffer solution" in line 11. There is insufficient antecedent basis for this limitation in the claim;

g) Claim 1 recites the limitation "the resulting spaces" in line 12. There is insufficient antecedent basis for this limitation in the claim;

h) Claim 1, lines 3-7 are confusing because mention is first made of arranging gels, then polymerizing and then rehydrating. Is not a gel already polymerized? Also, rehydrating implies a prior dehydration, which has not been indicated.

i) Claim 1, line 12: -- gels -- should be inserted between "dimension" and "and";

j) Claim 1, line 12: what is polymerized out?

k) Claim 1, line 16: -- second dimension -- should be inserted between "the" and "gels";

l) Claim 1, lines 11-12: if "contact gel is filled into the resulting spaces between the first and second dimension" what does it mean for the gel, which is already polymerised, to be "polymerized out"?

m) Claim 1 recites the limitation "the proteins" in line 16. There is insufficient antecedent basis for this limitation in the claim;

n) Claim 2, line 3 refers to "the separation process". There are two separation processes in Claim 1, a first dimension separation and a second dimension separation. Which separation process is being referred to?;

o) Claim 2 requires the gels in the combination chamber to be standing vertically, yet the separation in the second dimension is performed horizontally. This appears to be inconsistent;

p) Claim 3 recites the limitation "the separation gel" in line 4. There is insufficient antecedent basis for this limitation in the claim;

r) Claim 3 recites the limitation "the polymerisation processes" in line 5. There is insufficient antecedent basis for this limitation in the claim;

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- s) Claim 3, lines 3-4: the phrase "in such a way that, in a first step a sealing gel," is incomplete. What happens or does not happen to the sealing gel in the first step?
- t) Claim 3 recites the limitation "its polymerisation" in line 4. There is insufficient antecedent basis for this limitation in the claim;
- u) Claim 3 recites the limitation "gel solution" in line 4. There is insufficient antecedent basis for this limitation in the claim;
- v) Claim 3, lines 4-5: "cast from below" what?
- w) Claim 3, line 6: is not a gel already a polymerized material?
- x) Claim 5, line 3: should "variable width and thickness" be -- different widths and thicknesses --;
- y) Claim 6 recites the limitation "neutralization of the isolation_s [emphasis added]" in line 2. There is insufficient antecedent basis for this limitation in the claim;
- z) Claim 6 recites the limitation "seals" in line 2. There is insufficient antecedent basis for this limitation in the claim;

aa) Claim 6 recites the limitation "seal hoses" in line 4. There is insufficient antecedent basis for this limitation in the claim;

ab) Claim 6, lines 3-4: "switching by means of volume or diameter reductions of seal hoses" is unclear;

ac) Claim 7: does "the process of the two-dimensional electrophoresis" refer to the entire method of Claim 1?

ad) Claim 8, line 3: what is meant by "tempered"?

ae) Claim 9, lines 1-2: "biomolecules or other substance mixtures" should be -- mixtures of biomolecules or other substances --;

af) Claim 9, lines 1-3: how does an electrophoresis apparatus indicate electrodes?

ag) Claim 9: it is not clear which elements the isolating elements are in "combination" with?

ah) Claim 9: what are the isolating elements isolating?

ai) Claim 9: are each of the isolating elements in the form of a hollow seal?

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aj) Claim 12, line 3: "secured on both sides" of the core?

ak) Claim 13 recites the limitation "lower limitation" in line 3. There is insufficient antecedent basis for this limitation in the claim;

al) Claim 13, line 4: should "adjustable and rotary table" be -- adjustable rotary table -- or -- adjustable and rotatable table --?

am) Claim 13 recites the limitation "the cover" in line 5. There is insufficient antecedent basis for this limitation in the claim;

an) Claim 13, line 5: is "indicates" meant to also mean -- comprises --?

ao) Claim 13 recites the limitation "the connections for the electrodes" in line 7. There is insufficient antecedent basis for this limitation in the claim;

ap) Claim 13 recites the limitation "the electrodes of the first and second dimension" in line 7. There is insufficient antecedent basis for this limitation in the claim;

aq) Claim 14, line 4: "vent openings are arranged" where?

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ar) Claim 14, line 5: are the "inner plates (4) and outer plates (5)" of Claim 9 being referred to?

as) Claim 14, line 6: recesses have to exist in something;

at) Claim 14 recites the limitation "the parts of the electrophoresis combination chamber (1) contacting the media gels and /or gel solutions and/or buffer solutions" in lines 6-8. There is insufficient antecedent basis for this limitation in the claim;

au) Claim 14 recites the limitation "the media gels and/or gel solutions" in line 7. There is insufficient antecedent basis for this limitation in the claim;

av) Claim 15, lines 1-2: "biomolecules or other substance mixtures" should be -- mixtures of biomolecules or other substances --;

av) Claim 15, line 5: what are "assembly groups"?

aw) Claim 15, lines 9-10: are all of the isolating elements in the form of a hollow seal?

ay) Claim 15 recites the limitation "the electrodes" in line 10. There is insufficient antecedent basis for this limitation in the claim;

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az) Claim 16, lines 1-2: "biomolecules or other substance mixtures" should be -- mixtures of biomolecules or other substances --;

ba) Claim 16, lines 2-3: "by means of electrophoresis" should be relocated to between "mixtures" and "in" in line 2;

bb) Claim 16: it is not clear whether the rear wall plate and the cover plate are being used to horizontally arrange the gels;

bc) Claim 16, line 4: -- the -- should be inserted between "between" and "rear";

bd) Claim 16, line 4: -- the -- should be inserted between "and" and "cover";

be) Claim 16 recites the limitation "chamber arrangement" in line 3. There is insufficient antecedent basis for this limitation in the claim;

bf) Claim 17, lines 5-6 require gels to be arranged horizontally above each other. Are these gels different from the gels of Claim 16, which are arranged horizontally above each other?

bg) Claim 18 recites the limitation "the upper buffer reservoir" in line 3. There is insufficient antecedent basis for this limitation in the claim;

bh) Claim 18 recites the limitation "the pouring vessel" in line 4. There is insufficient antecedent basis for this limitation in the claim;

bi) Claim 18 recites the limitation "the buffer filling vessel" in line 4. There is insufficient antecedent basis for this limitation in the claim;

bj) Claim 18 recites the limitation "the lower buffer tank" in line 7. There is insufficient antecedent basis for this limitation in the claim;

bk) Claim 18, lines 5-7 requires the *upper* buffer reservoir to be in the *lower* buffer tank. It is not clear what physical orientations "upper" and "lower" are to confer? Is the upper buffer reservoir the upper buffer reservoir of the lower buffer tank?

bl) Claim 18, lines 7-8: what does "liftable in function" mean?

bm) Claim 19, line 1: "biomolecules or other substance mixtures" should be -- mixtures of biomolecules or other substances --;

bn) Claim 19, lines 9 and 12: is not an SDS-gel already polymerised

bo) Claim 19, line 14: what resulting spaces?

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bp) Claim 19 recites the limitation "the known methods" in line 16. There is insufficient antecedent basis for this limitation in the claim;

bq) Claim 20, line 3: although Claim 19 provides a re-hydration coating, there is not rehydrating step;

br) Claim 20 recites the limitation "the recess in the IEF-gel" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim;

bs) Claim 20: is the plastic hose, whose removal neutralizes the isolation, the same as the hollow seal of claim 19, which created the isolation?

bt) Claim 20, line 5: which electrophoresis (IEF or SDS)?

bu) Claim 21 recites the limitation "the cooling" in line 3. There is insufficient antecedent basis for this limitation in the claim;

bv) Claim 21 recites the limitation "the gel sandwiches" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim;

bw) Claim 21 is the rehydration buffer mixed with and/or the same as the buffer solution of the second dimension?

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bx) Claim 22 recites the limitation "the biomolecule or substance mixture *specimen* [emphasis added]" in line 2. There is insufficient antecedent basis for this limitation in the claim;

bz) Claim 23, lines 1-2: "biomolecules or other substance mixtures" should be -- mixtures of biomolecules or other substances --;

ca) Claim 23 recite the limitation "the gel for the separation in the first dimension as well as the isolating element" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim;

cb) Claim 23: are "various specimens" related to "biomolecules or other substance mixtures"?

cc) Claim 23 recite the limitation "the SDS-gel" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim;

cd) Claim 23, line 6: are the specimens polymerised out of the specimen pockets?

ce) Claim 23, line 8: what resulting recesses?

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cf) Claim 23: after the specimens are polymerized out of the specimen pockets where are the specimens and how do they get to the resulting recesses?

cg) Claim 24, lines 1-2: is not the immobiline-gel already polymerized?

ch) Claim 24, lines 2-3: is not the acryl amide gel already polymerized?

ci) Claim 24, lines 3-4: is not the immobiline-gel already polymerized?

cj) Claim 24, line 4: "re-hydration" implies previous dehydration, which is not indicated?

ck) Claim 24 recite the limitation "such ampholines" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim;

cl) Claim 25, line 3: is 6-10% or 10% being claimed?

cm) Claim 25, line 3: what is the unit (vol%, e.g.) for 6-10%?

cn) Claim 26, line 3: is 3.5-4.5% or 3.5-5% being claimed?

co) Claim 26, line 3: what is the unit (vol%, e.g.) for 3.5-4.5%?

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- cp) Claim 27, line 3: is 5-9.5 M or 3.5-5 M being claimed?
 - cq) Claim 28, line 2: what is dried?
 - cr) Claim 29, lines 1-2: is not the immobilized-gel already polymerized?
 - cs) Claim 29, lines 2-3: is not the acryl amide gel already polymerized? and
 - ct) Claim 29, lines 3-4: is not the immobilized-gel already polymerized?
12. Note that dependent claims will have the deficiencies of base and intervening claims.
- Allowable Subject Matter*
13. Claims 19, 24, and 29 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action.
14. Claims 20-22 and 25-28 would be allowable if rewritten to overcome the rejections under

35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 19 requires the IEF-gel and the SDS-gel in the electrophoresis combination chamber to be isolated from each other by a hollow seal. In Hochstrasser (US 5,773,645) when the first dimension gel and the single second dimension gel are isolated they are isolated by a wall (23) of an enclosure (21), which encloses the first dimension gel, not by a hollow seal;

b) Claims 20-22 depend from allowable Claim 19; and

c) Claims 24 and 29 require a sandwich arrangement of gels comprising two outer layers of immobilized gel and an intermediate layer comprising acryl amide gel in contact with the two outer layers. In Faupel et al. (US 5,082,548) there is no intermediate gel layer between the immobilized gels in containers 5 and 12 (Figure 8 and col. 3, ln. 46 – col. 6, ln. 24). Container 8, which is intermediate containers 5 and 12, is a flow cell into which the mixture to be separated is introduced (abstract).

Specification

16. The abstract should be 150 words or less. MPEP 608.01(b).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguera

Alex Noguera

02/11/04

Primary Examiner

TC 1753